

REMARKS

This paper is submitted in Response to the Restriction Requirement for the above-identified application mailed July 30, 2002.

In Response to this Restriction Requirement, Claims 2-21 are amended, Claims 22-30 are cancelled. New Claim 31, a new independent claim, is added.

In the Restriction Requirement the claims were divided into four groups, Claims 1-17, 18-21, 22-26 and 27-30.

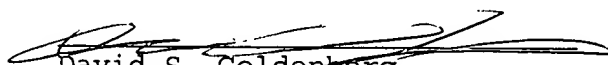
Claim 31, like Claim 1, is directed to a screening device for interpreting the lines of immunoassay test. Therefore, it is respectfully submitted that this claim should be considered a Group I claim.

The Applicants respectfully traverse the Restriction Requirement with regards to the Groups I and II claims, Claims 1-21. Specifically, Claim 18, as amended, is directed to a screening device that, like the screening device of Claim 1, is used to perform an immunoassay test. The components of this screening device recited by Claim 18 are similar to the components of the screening device recited by Claim 1.

Accordingly, since Claim 18, like Claim 1, is directed to a screening device for interpreting an immunoassay test, and has components similar to that of the screening device of Claim 1, it is respectfully submitted that no additional burden is placed upon the Trademark Office for having Claim 18 substantively reviewed with Claim 1.

Nevertheless, in the event the Examiner charged with review of this application reaches an alternative conclusion, the Applicants hereby elect to proceed with the examination of the Group I claims, Claims 1-17 and 31.

Respectfully submitted,


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2. (Amended) AThe screening device according to claim 1, wherein said second data processor compares said control data, background data and test data to determine whether said test data exhibits a statistically significant result compared to said control data and background data.

3. (Amended) AThe screening device according to claim 1, wherein said second data processor is provided with null data, said null data being representative of the intensity of light reflected from said background areas between said lines, said second data processor comparing said test data and said null data to determine whether said test data exhibits a statistically significant result.

4. (Amended) AThe screening device according to claim 1, wherein a timer is provided for delaying said illumination of said immunoassay test until said immunoassay test has been completed.

5. (Amended) AThe screening device according to claim 1, wherein said first and second data processors are provided by a central processor unit.

6. (Amended) AThe screening device according to claim 5, wherein serial and parallel ports are provided from said central processor unit to allow said screening device to be controlled from an external processor or to allow said screening device to download the results of said comparison of the control data, background data and test data.

7. (Amended) AThe screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a charge coupled device, associated video digitiser and video data interface.
8. (Amended) AThe screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a CMOS imaging sensor, associated driver and video buffer.
9. (Amended) AThe screening device according to claim 1, wherein said output is a display.
10. (Amended) AThe screening device according to claim 1, wherein said immunoassay test is conducted on a saliva sample.
11. (Amended) AThe screening device according to claim 1, wherein said immunoassay test is performed in a disposable test cartridge.
12. (Amended) AThe screening device according to claim 1, wherein said first data processor includes a filter for filtering said data array prior to determining whether said test zones exhibit statistically significant results.
13. (Amended) AThe screening device according to claim 1, wherein a timer, coupled to said first processor produces a delay before said first processor segments the data.
15. (Amended) AThe method of screening an immunoassay test according to claim 14, wherein said threshold is set by reference to said first and third pluralities of data.

16. (Amended) AThe method of screening an immunoassay test according to claim 14, wherein said immunoassay test is conducted on a saliva sample.

17. (Amended) AThe method of screening an immunoassay test according to claim 14, wherein said outputted results are displayed on a liquid crystal device.

18. (Amended) A screening device for interpreting the results of an immunoassay test in the form of an agglutination test, said test having areas of coagulation and background areas, said device comprising:

- a light source for illuminating said test;
- an array of photosensitive detectors for detecting the intensity of light from said light source which is reflected from said areas of coagulation and background areas of said agglutination test;

- a digitiser, coupled to the output of said array of photosensitive detectors, for representing said intensity of the detected light by a data array;

- a threshold processor, coupled to the output of said digitiser, for thresholding said digitised data to distinguish between background areas and areas of coagulation;

- a first data processor, coupled to said threshold processor, for identifying from said thresholded data areas of coagulation and estimating the size of said areas of coagulation;

- a second data processor, coupled to the output of said first data processor, for determining whether said areas of coagulation exhibit a statistically significant result; and

an output, coupled to said second data processor,
for outputting the results from said second data
processor.

19. (Amended) AThe screening device according to claim
18, wherein a noise reduction processor is coupled
between the output of said digitiser and said first data
processor for performing noise reduction on said
digitised data.

20. (Amended) AThe method of screening an
agglutination test, said test having areas of coagulation
and background areas, said method comprising the steps
of:

- illuminating said test;
- detecting the intensity of light which is
reflected from said areas of coagulation and background
areas of said agglutination test;
- representing the intensity of said detected light
in a data array;
- thresholding said data array to distinguish
between background areas and areas of coagulation;
- identifying areas of coagulation and estimating
the number of said areas of coagulation;
- determining whether said areas of coagulation
exhibit a statistically significant result; and
- outputting said results.

21. (Amended) AThe method according to claim 20,
wherein noise reduction of said digitised data is
performed prior to thresholding said digitised data.

1. A screening device for interpreting the lines of an immunoassay test having discretely located test zones and a control zone interposed between background zones, said device comprising:

a light source for illuminating an immunoassay test;

an array of photosensitive detectors for detecting the intensity of light which is reflected from said test zones, control zone and background zones of said immunoassay test;

a digitiser, coupled to the output of said array of photosensitive detectors, for representing said intensity of detected light by a data array;

a store for storing preset data;

first data processor, coupled to said store and to the output of said digitiser, for segmenting said data array according to said preset data into control data, background data and test data;

a second data processor, coupled to said first data processor, for determining whether said test data exhibits a statistically significant result; and

an output, coupled to the output of said second data processor, for outputting the results from said second data processor.

2. (Amended) The screening device according to claim 1, wherein said second data processor compares said control data, background data and test data to determine whether said test data exhibits a statistically significant result compared to said control data and background data.

3. (Amended) The screening device according to claim 1, wherein said second data processor is provided

with null data, said null data being representative of the intensity of light reflected from said background areas between said lines, said second data processor comparing said test data and said null data to determine whether said test data exhibits a statistically significant result.

4. (Amended) The screening device according to claim 1, wherein a timer is provided for delaying said illumination of said immunoassay test until said immunoassay test has been completed.

5. (Amended) The screening device according to claim 1, wherein said first and second data processors are provided by a central processor unit.

6. (Amended) The screening device according to claim 5, wherein serial and parallel ports are provided from said central processor unit to allow said screening device to be controlled from an external processor or to allow said screening device to download the results of said comparison of the control data, background data and test data.

7. (Amended) The screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a charge coupled device, associated video digitiser and video data interface.

8. (Amended) The screening device according to claim 1, wherein said array of photosensitive detectors and said digitiser are provided by a CMOS imaging sensor, associated driver and video buffer.

9. (Amended) The screening device according to claim 1, wherein said output is a display.

10. (Amended) The screening device according to claim 1, wherein said immunoassay test is conducted on a saliva sample.

11. (Amended) The screening device according to claim 1, wherein said immunoassay test is performed in a disposable test cartridge.

12. (Amended) The screening device according to claim 1, wherein said first data processor includes a filter for filtering said data array prior to determining whether said test zones exhibit statistically significant results.

13. (Amended) The screening device according to claim 1, wherein a timer coupled to said first processor produces a delay before said first processor segments the data.

14. A method of screening an immunoassay test having discretely located test zones and a control zone interposed between background zones where the result of said test is indicated by the amount of a marker deposited in said test zones compared to said background and control zones, said method comprising the steps of:

illuminating said immunoassay test;

detecting the intensity of light reflected from said control zone, test zones and interposed background zones of said immunoassay test and converting said detected intensity to a data array;

segmenting said data array into first, second and third pluralities of data, said first plurality of data

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corresponding to said control zone, said second plurality of data corresponding to said test zones, said third plurality of data corresponding to said background zones; processing said second plurality of data to determine whether said second plurality of data shows a substance level above a threshold; and outputting the results of said processing.

15. (Amended) The method of screening an immunoassay test according to claim 14, wherein said threshold is set by reference to said first and third pluralities of data.

16. (Amended) The method of screening an immunoassay test according to claim 14, wherein said immunoassay test is conducted on a saliva sample.

17. (Amended) The method of screening an immunoassay test according to claim 14, wherein said outputted results are displayed on a liquid crystal device.

22 18. (Amended) A screening device for interpreting the results of an immunoassay test in the form of an agglutination test, said test having areas of coagulation and background areas, said device comprising:

a light source for illuminating said test;

an array of photosensitive detectors for detecting the intensity of light from said light source which is reflected from said areas of coagulation and background areas of said agglutination test;

a digitiser, coupled to the output of said array of photosensitive detectors, for representing said intensity of the detected light by a data array;

a threshold processor, coupled to the output of said digitiser, for thresholding said digitised data to

distinguish between background areas and areas of coagulation;

a first data processor, coupled to said threshold processor, for identifying from said thresholded data areas of coagulation and estimating the size of said areas of coagulation;

a second data processor, coupled to the output of said first data processor, for determining whether said areas of coagulation exhibit a statistically significant result; and

an output, coupled to said second data processor, for outputting the results from said second data processor.

19. (Amended) The screening device according to claim 18, wherein a noise reduction processor is coupled between the output of said digitiser and said first data processor for performing noise reduction on said digitised data.

20. (Amended) The method of screening an agglutination test, said test having areas of coagulation and background areas, said method comprising the steps of:

illuminating said test;

detecting the intensity of light which is reflected from said areas of coagulation and background areas of said agglutination test;

representing the intensity of said detected light in a data array;

thresholding said data array to distinguish between background areas and areas of coagulation;

identifying areas of coagulation and estimating the number of said areas of coagulation;

determining whether said areas of coagulation exhibit a statistically significant result; and

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outputting said results.

21. (Amended) The method according to claim 20, wherein noise reduction of said digitised data is performed prior to thresholding said digitised data.

31. (New) A screening device for interpreting the lines of an immunoassay test having discretely located test zones and a control zone interposed between background zones, said device comprising:

illuminating means for illuminating an immunoassay test,

an array of photosensitive detector means for detecting the intensity of light from said illuminating means which is reflected from said test zones, control zone and background zones of said immunoassay test;

any means, coupled to the output of said array of photosensitive detector means, for representing said intensity of detected light by a data array;

memory means for storing preset data;

data processing means, coupled to the memory means and to the output of the means, for:

(i) representing the intensity of said detected light by a data array, for segmenting said data array according to said preset data into control data, background data and test data; and

(ii) comparing said control data, background data and test data to determine whether said test data exhibits a statistically significant result compared to said control data and background data; and

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output means, coupled to the output of said data processing means, for outputting the results of said

no digitisation
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comparison of control data, background data and test data
from said data processing means.
